

NOV - 3 2003

October 30, 2003

Device Name:

ATAC HemoglobinA1C Reagent

K031042

Summary of 510(k) Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC HemoglobinA1C Reagent Kit is intended for the quantitative determination of HemoglobinA1C in whole blood. HemoglobinA1C results are used in monitoring glycemic control in diabetic patients. The assay determines total hemoglobin and μ mole A1C. These values are then used in the calculation of %Hemoglobin. The ATAC Hemoglobin A1C reagent is substantially equivalent to the Bayer HemoglobinA1C reagent, Bayer product no. T01-3639-01, currently marketed by Bayer Corporation, Tarrytown, New York.

The effectiveness of the ATAC HemoglobinA1C Reagent Kit on the ATAC 8000 Random Access Chemistry System is shown by the following studies.

Analyzing A1C calibrators run as unknowns validated Bayer linearity claims. Total hemoglobin linearity was validated using hemolysates that spanned the range of zero to 23 g/dL.


Precision is demonstrated by the replicate assay of Bayer DCA 2000 Controls and a pooled patient sample. Precision statistics, calculated analogous to the methods described in NCCLS Guideline EP-6P, are shown below.

Sample	n	mean	Within Run		Total	
			1SD	%CV	1SD	%CV
Control 1	32	5.581	0.189	3.38	0.265	4.74
Control 2	31	10.345	0.254	2.46	0.318	3.08
Patient	31	6.777	0.176	2.60	0.316	4.66

Whole blood samples collected from patients and were assayed using the ATAC 8000 Random Access Chemistry System and by TOSOH HPLC method. Results were compared by least squares linear regression and the following statistics were obtained.

$$\text{ATAC 8000} = 0.6367 + 0.9722 \times \text{Comparative Method}$$

The 12 day calibration stability claim and 10 day on board stability claim are documented through the assay of controls and a pooled patient sample over the claimed periods. In all cases, the total imprecision of %HemoglobinA1C recoveries over the test periods are less than 5%.


Wynn Stocking
Manager, Regulatory Affairs
Clinical Data, Inc.
Brea, California
714-672-3553



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Wynn Stocking
Manager, Regulatory Affairs
Clinical Data, Inc.
1075 W. Lambert Road
Building D
Brea, CA 92821

Re: k031042
Trade/Device Name: ATAC HemoglobinA1C Reagent
Regulation Number: 21 CFR 864. 7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: August 6, 2003
Received: August 7, 2003

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

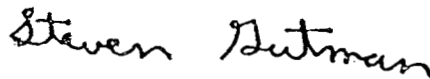
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031042

Device Name: ATAC Hemoglobin A1C Reagent

Indications for Use:

The ATAC Hemoglobin A1C Reagent Kit is intended for use with the ATAC 8000 Random Access Chemistry System as a system for the quantitative determination of Hemoglobin A1C in blood. Hemoglobin A1C results are used to assess the level of control of a patient's diabetes.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (PDE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K031042